

**IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

COMPASS LABORATORY SERVICES,)	
LLC,)	
Plaintiff,)	
v.)	No. 2:22-cv-2770-SHL-atc;
XAVIER BECERRA, in his official capacity)	No. 2:23-cv-2018-SHL-cgc
as Secretary, United States Department of)	
Health and Human Services,)	
Defendant.)	

**ORDER GRANTING IN PART THE SECRETARY’S MOTION FOR
SUMMARY JUDGMENT AND DENYING COMPASS’S MOTION FOR
SUMMARY JUDGMENT**

Before the Court are Plaintiff Compass Laboratory Services, LLC’s (“Compass”) motion for summary judgment (ECF No. 46), filed August 4, 2023, Defendant Xavier Becerra’s (in his official capacity as Secretary of the United States Department of Health and Human Services) (“Secretary”) response (ECF No. 51), filed August 31, 2023, Compass’s reply (ECF No. 58), filed September 14, 2023, the Secretary’s motion for summary judgment (ECF No. 49), filed August 4, 2023, Compass’s response (ECF No. 53), filed September 1, 2023, and the Secretary’s reply (ECF No. 56), filed September 14, 2023. All documents were filed in identical form on both dockets; the Court cites to the docket in Case No. 2:22-cv-2770-SHL-atc for simplicity. For the reasons described below, the Secretary’s motion is **GRANTED IN PART** and Compass’s motion is **DENIED**.

BACKGROUND¹

The scheduling order outlined two separate deadlines for dispositive motions; this round of cross motions for summary judgment pertains to the consolidated legal issues (or, more appropriately, common issues among all three audits) and not potential issues with the individual claims in each case. (ECF No. 33 at PageID 155.) These two related cases were consolidated for purposes of their identical first two counts.

Compass, a provider of diagnostic laboratory services, was audited on behalf of the Centers for Medicare & Medicaid Services (“CMS”) concerning reimbursements Compass received on Medicare Part B claims. (ECF No. 50 at PageID 509; ECF No. 47 at PageID 253.) AdvanceMed Corporation (“AdvanceMed”) was the Zone Program Integrity Contractor (“ZPIC”) that conducted the data analysis and statistical sampling during three separate audits in 2015–16. (ECF No. 47 at PageID 253–54.) This sampling used extrapolation to reach conclusions that CMS overpaid Compass estimated amounts that totaled \$9,266,990.53 (“\$9 million matter”) in the first audit, \$3,354,936.48 (“\$3 million matter”) in the second, and \$1,231,973.77 (“\$1 million matter”) in the third. (*Id.* at PageID 254–55.)

Each matter involved the same approach to the statistical analysis of claims but covered different time periods. The \$9 million matter covered testing services that Compass conducted on behalf of Medicare beneficiaries from January 2012 through the end of January 2014; using a representative sample size, AdvanceMed found a 100% error rate totaling \$9,546.83 in overpayments across sixty-four claims. (*Id.* at PageID 255.) The sample was then extrapolated

¹ Although the administrative record is controlling for factual purposes, *see* 42 U.S.C. § 1395, the Parties agree that it is too “voluminous” to file on the docket and “contain[s] confidential healthcare information.” (ECF No. 39 at PageID 179.) Thus, the Court cites to the filings of the Parties that describe information in the administrative record and the ALJ decisions at issue.

out across 47,687 sampling units that had 417,225 sampling unit lines (“lines”) and non-zero payment amounts ranging from \$2.74 to \$731.82. (Id. at PageID 256.) Notably, 128,444 lines had a paid amount of \$0. (Id.)

The \$3 million matter concerned sixty-six claims utilizing 29,278 sampling units with 274,851 lines (116,391 of which had a \$0 paid amount) that had non-zero payments between \$2.72 and \$316.69 for services rendered from February 2014 through the end of September 2014. (Id. at PageID 257.) Lastly, the \$1 million matter encompassed forty-eight claims relying on 11,313 sampling units with 48,725 lines (all of which were paid, meaning there were no \$0 paid amount) that had payments between \$2.20 to \$343.09 for diagnostic testing conducted between October 2014 and January 26, 2015. (Id. at PageID 258–59.)

To challenge the results of these audits, Compass embarked on what is typically a five-step appeals process that began with an unfavorable redetermination decision upholding the sampling and extrapolation in all three audits. (Id. at PageID 259; ECF No. 50 at PageID 509.) Next, a qualified independent contractor also upheld the results. (ECF No. 50 at PageID 509.) Compass then appealed to the Office of Medicare Hearings and Appeals. (Id.)

After consolidating the \$9 million matter and the \$1 million matter, Administrative Law Judge (“ALJ”) Kevin McCormick found “no basis to overturn the statistical sampling and extrapolation” used by AdvanceMed. (Id. at PageID 510; No. 2:23-cv-2018, ECF No. 1-1 at PageID 68.) ALJ Steven Parrish reached the same determination on the sampling protocols for the \$3 million matter. (ECF No. 50 at PageID 510.) The typical fourth step in the appellate process is a review of the ALJ decisions by the Medicare Appeals Council (“MAC”). (Id.) Compass pursued that path, but when the MAC did not issue a decision within ninety days, Compass sought judicial review (id. at PageID 510–11), by filing its complaint in the District of

Columbia on August 4, 2022 (ECF No. 1). This case was then transferred to the Western District of Tennessee on November 8, 2022. (ECF No. 11.)

The two counts consolidated here are, in Compass’s words: “Count One: AdvanceMed’s Failure to Produce the Universe of Claims in its Statistical Sampling Violated Plaintiff’s Right to Due Process. . . . Count Two: AdvanceMed’s Failure to Include *Unpaid* Claims in its Statistical Sampling Violated Plaintiff’s Right to Due Process.” (ECF No. 1 at PageID 45–46) (emphasis added). However, Compass has since finetuned its adjectives, focusing on the treatment of zero-paid claims in the audits.

Unpaid claims are claims that have yet to be fully adjudicated, and therefore the payment amount, if any, is unknown at the time of the audit. (See ECF No. 46-1 at PageID 242.) Unpaid claims are, to use a judicial term of art that is just as equally understood in produce departments, not yet ripe for consideration within the universe of potential claims. Zero-paid claims, on the other hand, are claims that CMS deemed unworthy of any reimbursement whatsoever—in other words, Compass received no monetary compensation on a fully-adjudicated reimbursement attempt. (See ECF No. 46-1 at PageID 242; ECF No. 51 at PageID 517.) While agreeing that unpaid claims should not be included in the sampling, Compass argues that the exclusion of zero-paid claims deprived them of a property interest; the Secretary disagrees.

The Secretary also argues additional legal issues in its motion that are not addressed by Compass. (ECF No. 56 at PageID 570.) While these issues may be relevant to both complaints, as stated by the Secretary, they were not specifically consolidated for consideration under this case number as counts one and two were. Therefore, this Order will not address 1) interest accrued or 2) the potential improper recoupment of overpayments, but the Secretary is free “to make his arguments again at a later juncture.” (See id. at PageID 571.)

STANDARD OF REVIEW

Summary judgment is proper “if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” Fed. R. Civ. P. 56(a). The court views the facts in the record and reasonable inferences that can be drawn from those facts in the light most favorable to the nonmoving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986).

The party opposing summary judgment must show that there is a genuine dispute of material fact by pointing to evidence in the record or argue that the moving party is not entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a), (c)(1). “When confronted with a properly supported Motion for Summary Judgment, the party with the burden of proof at trial is obligated to provide concrete evidence supporting its claims and establishing the existence of a genuine issue of fact.” Cloverdale Equip. Co. v. Simon Aerials, Inc., 869 F.2d 934, 937 (6th Cir. 1989) (citing Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986)). The opposing party “cannot rest solely on the allegations made in her pleadings.” Skousen v. Brighton High Sch., 305 F.3d 520, 527 (6th Cir. 2002).

When both parties move for summary judgment, “the standards upon which the court evaluates the motions for summary judgment do not change simply because the parties present cross-motions.” See Taft Broad. Co. v. United States, 929 F.2d 240, 248 (6th Cir. 1991). “[T]he court must evaluate each party’s motion on its own merits, taking care in each instance to draw all reasonable inferences against the party whose motion is under consideration.” Id. (quoting Mingus Constructors, Inc. v. United States, 812 F.2d 1387, 1391 (Fed. Cir. 1987)).

However, just because both parties move for summary judgment, it is “not necessary for the district court to resolve the case at summary judgment . . . [because] the making of such

inherently contradictory claims does not constitute an agreement that if one is rejected the other is necessarily justified.” B.F. Goodrich Co. v. U.S. Filter Corp., 245 F.3d 587, 593 (6th Cir. 2001) (citation omitted). “A trial court may conclude . . . that a genuine issue exists as to those material facts, in which case the court is not permitted to resolve the matter” at the summary judgment stage. Id.

Here, both Parties seek summary judgment within the context of judicial review of an administrative agency decision. Under the Administrative Procedure Act (“APA”), a “reviewing court shall . . . hold unlawful and set aside agency action, findings, and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law.” 5 U.S.C. § 706 (2)(A). The reviewing court “must consider whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” See Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971).

More specific to this context, when reviewing final agency decisions rendered by the Department of Health and Human Services under 42 U.S.C. § 1395ff(b)(1) (which incorporates 42 U.S.C. § 405(g)), district courts view the administrative record² in its entirety to determine if the final agency decision is supported by substantial evidence—a rather deferential standard.

² In our Order Denying Plaintiff’s Request for Defendant to Supplement the Administrative Records, the Court reasoned that the plain language of 42 U.S.C. § 405(g) limits review to “the pleadings and transcript of the record.” (ECF No. 45 at PageID 223.) Therefore, this case has a “closed administrative record” and “neither party may put any additional evidence before the district court.” (Id.) (quoting Mathews v. Weber, 423 U.S. 261, 270 (1976)).

On March 19, 2024, Compass filed a Motion for Revision of Interlocutory Order, relying on a District of South Carolina interlocutory order’s reasoning on what can be considered a part of the record for review as a “change in law” that this Court should consider under Fed. R. Civ. P. 54(b). (ECF No. 63-1 at PageID 622.) This motion is not yet ripe, but the Court acknowledges its receipt and notes that it is unlikely to have an impact on this Order because the purported “change in law” was simply another district court’s stance on an issue previously ruled on here.

See General Medicine, P.C. v. Azar, 963 F.3d 516, 519–20 (6th Cir. 2020). Substantial evidence is “more than a mere scintilla[; i]t means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion.” Richardson v. Perales, 402 U.S. 389, 401 (1971). If the reviewing court finds that level of evidence, then the agency decision “must be affirmed even if the reviewing court would decide the matter differently . . . and even if substantial evidence also supports the opposite conclusion.” Cutlip v. Sec’y of Health & Hum. Servs., 25 F.3d 284 (6th Cir. 1994) (citations omitted).

“The findings of the [Secretary] as to any fact, if supported by substantial evidence, shall be conclusive.” 42 U.S.C. § 405(g). Errors of law, however, are reviewed de novo, and “we must reverse and remand if the ALJ applied incorrect legal standards, even if the factual determinations are otherwise supported by substantial evidence and the outcome on remand is unlikely to be different.” See Kalmbach v. Comm’r of Soc. Sec., 409 F. App’x 852, 859 (6th Cir. 2011); see also General Medicine, P.C. v. Azar, 963 F.3d 516, 520 (6th Cir. 2020).

ANALYSIS

Here, two ALJ decisions considered these audit findings. (See ECF No. 1-1 at PageID 52; No. 2:23-cv-2018, ECF No. 1-1 at PageID 68.) This Court reviews the portions of those decisions relevant to the issues at hand as findings of fact as opposed to questions of law. One could argue that whether zero-paid claims should be included in the universe of claims is a mixed question of fact and law, but it is not a purely legal question.

Other courts in this district have taken a similar approach when determining whether an argument within the CMS post-payment audit space is rooted in fact or law: “Nowhere does the case law indicate that every question regarding the application of the MPIM’s statistical sampling and extrapolation guidelines is a matter of law. . . . The ALJ’s findings were thus

findings of fact, not of law.” Methodist Healthcare Memphis Hosps. V. Becerra, No. 2:21-cv-2476, 2022 WL 4587170, at *5–6 (W.D. Tenn. Sept. 29, 2022). Even considering these issues as mixed questions, there is substantial evidence in the record to support these ALJ determinations, and the correct legal standards were applied as to the two issues currently before the Court.

I. Due Process Concerns

Medicare Part B beneficiaries—otherwise known as patients who are at least sixty-five years old or disabled—have a due process property interest in payments made on their behalf for medically necessary services that have already been rendered by a medical provider and that have been, in a way, paid in advanced through monthly premiums. See Himmler v. Califano, 611 F.2d 137, 145 (6th Cir. 1979); Bailey v. Mutual of Omaha Ins. Co., 534 F. Supp. 2d 43, 53–54 (D.C. Cir. 2008). Compass tries to embrace that property interest as their own in an unconvincing manner. (ECF No. 46-1 at PageID 239–240.) The Sixth Circuit has not taken a stance on whether providers like Compass have a due process property interest in CMS reimbursements. See A1 Diabetes & Med. Supply v. Azar, 937 F.3d 613, 619 (6th Cir. 2019). This Court will not take a stance either, and, instead, focuses on the second issue at the crux of the disagreement—if there was a hypothetical due process property interest, did the sampling procedures followed by the Secretary’s contractors comply with applicable statutory and regulatory guidance concerning the exclusion of zero-paid claims from the sample and ensuing extrapolation? The answer to this question controls the day here. Any potential due process property rights associated with other counts will be addressed in the future, as applicable.

II. Zero-Paid Claims: Impact on Sampling

Compass challenges the audit process, specifically the exclusion of zero-paid claims in sampling. Post-payment audits exist in part because reimbursement systems “as complex and

ripe with potential for abuse as Medicare” need to be monitored. See University of Cincinnati v. Heckler, 733 F.2d 1171, 1176 (6th Cir. 1984). An overarching goal of CMS-reimbursement audits is to determine “whether payment should not be, or should not have been, made . . . and [initiate] recovery of payments that should not have been made.” 42 U.S.C. § 1395ddd(b)(3). When conducting these audits, “CMS contractors will review the records and then calculate an error rate based on the review. If there is a sustained or high level of payment error, the CMS contractor will extrapolate that error rate over the provider’s total Medicare claims to determine a total amount of overpayment.” General Medicine, P.C. v. Azar, 963 F.3d 516, 519 (6th Cir. 2020).

This method of sampling and extrapolation has ample support in CMS administrative rulings, see CMS Rul. 86-1, Use of Statistical Sampling to Project Overpayments to Medicare Providers and Suppliers (Feb. 20, 1986), and in a robust manual—the Medicare Program Integrity Manual (“MPIM”)—that CMS issues for guidance around audits, sampling, and overpayment extrapolations, see MPIM Ch. 8 § 8.4.1.2 (Pub. No. 100-08, Rev. 377) (2011). The MPIM advises CMS contractors conducting this sampling on the granular steps to follow, including how to denote the parameters, identify a universe, and create sampling units. See MPIM Ch. 8 § 8.4.3.2.2–8.4.4.2.

The ALJ decisions here methodically document every step of the sampling and extrapolation procedures, as outlined in statutory and regulatory guidance, that were followed by AdvanceMed. (See ECF No. 1-1 at PageID 58–60; No. 2:23-cv-2018, ECF No. 1-1 at PageID 82–99, 355.) ALJ Parrish reasoned that “the ZPIC’s use of statistical sampling and overpayment extrapolation met the requirements of the MPIM or Section 1893(f)(7–8) of the Social Security Act. Therefore, the ZPIC’s use of statistical sampling to calculate extrapolated overpayment is

valid.” (ECF No. 1-1 at PageID 60.) Similarly, in a decision that ultimately was partially favorable to Compass on other grounds, ALJ McCormick noted that there is “no basis to overturn the statistical sampling and extrapolation in this case.” (No. 2:23-cv-2018, ECF No. 1-1 at PageID 355.)

Much of Compass’s argument comes down to a disagreement over how zero-paid claims are classified in sampling. The distinction between unpaid versus zero-paid claims is key to understanding Compass’s perspective: “Excluding ‘unpaid’ (i.e., ‘un-adjudicated’) claims is proper, but removal of adjudicated claims for which the payment amount was zero (i.e., ‘zero-paid’ claims) is not proper because they are potential underpayments.” (ECF No. 46-1 at PageID 242.) Barring zero-paid claims does indeed remove the possibility of finding, as part of this overpayment audit, potential *underpayments* with a paid-value of \$0.

However, the universe of claims need not include zero-paid claims: “The universe shall consist of all fully and partially paid claims submitted by the provider.” MPIM Ch. 8 § 8.4.3.2.1. A zero-paid claim is neither a fully paid or partially paid claim because there is no payment associated with a zero-paid claim whatsoever. In fact, there are separate avenues available to diagnostic lab companies like Compass to challenge claims with a zero-paid value. See 42 C.F.R. § 405.921(b). The remittance advice that providers receive outlines how one can pursue an appeal for a denied payment. See 42 C.F.R. § 405.921(b)(2)(ii).

ALJ McCormick’s decision aligns with these guidelines by emphasizing the language of MPIM Ch. 8 § 8.4.3.2.1 that calls for “all fully and partially paid claims” to be in the universe. (No. 2:23-cv-2018, ECF No. 1-1 at PageID 96.) McCormick quoted a MAC M-15-83 decision that held: “A contractor need not audit zero-paid claims that the provider or other party chose not to appeal, or that were billed as ‘no pay’ claims in the first place. This does not result in a biased

sample, so long as the contractor identifies any underpayment in the claims actually reviewed.”

(Id. at PageID 97.) McCormick then reached his own finding that “the ZPIC and the QIC did not err by excluding ‘zero paid claims.’” (Id.)

The Secretary quotes extensively from seven decisions made by the MAC that are in line with the ALJ decisions at bar. (ECF No. 49 at PageID 460–61.) Those MAC decisions resoundingly support the factual determination that zero-paid claims can and should be excluded from a sample because “the MPIM contemplates and allows that a valid statistical sample . . . may exclude underpayments and zero payments without affecting the sample validity.” Open Arms Home Care, Inc., No. M–11–2605, 2013 WL 8913143, at *12 (Medicare Appeals Council Sept. 17, 2023). Thus, substantial evidence exists to support the ALJ decisions.

When probing a bit further, the factual determinations made by the ALJs make sense to a healthcare layperson—as most federal district judges are—tasked with reviewing the administrative expertise of those that deal with CMS-related appeals for a living. If zero-paid claims were included in the sampling universe, perverse incentives would be in place for companies seeking CMS reimbursement. Diagnostic testing companies could, in theory, submit claims that have little to no hope of being repaid for two different reasons. First, they hope for reimbursement wherever they can get it. Second, the more total claims that are considered, the less of an impact any overpaid claim will have. The higher the denominator—or the more claims included in the universe for the eventual sample to be selected from—the better the odds of diminishing the extrapolating impact of overpayments for the provider seeking reimbursement.

Compass also argues that not accounting for zero-paid claims affects their rights because only potential overpayments and satisfactory payments, and not potential underpayments, are taken into account. (ECF No. 46-1 at PageID 244.) However, that is not the case. An

overpayment-focused audit *does* account for underpayments from the standpoint that they are not considered *overpayments*, and therefore Compass would not get penalized for an overpayment on that sampling unit. The Court looks to language that Compass quotes, with rearranged emphasis: “Sampling units that are found to be underpayments, in whole or in part, are recorded as negative overpayments and shall be **used in calculating the estimated overpayment.**” MPIM Ch. 8 § 8.4.5; (ECF No. 46-1 at PageID 242) (emphasis rearranged). This language should come as no surprise because the purpose of conducting the statistical sampling is to “estimate the amount of overpayment(s) made on claims.” MPIM Ch. 8 § 8.4.1.2. While they may not see a financial inflow coming their way because of any underpayment, a diagnostic lab company who received solely underpayments across the board would have a crystal clean audit with no penalties owed to the Secretary.

Importantly, there is a separate redetermination process that can be pursued for zero-paid claims if a provider is unsatisfied upon initial determination. See 42 C.F.R. § 405.921(b) (“The notice of initial determination must contain . . . [i]nformation on the right to a redetermination if the provider or supplier is dissatisfied with the outcome of the initial determination.”). However, that is not the purpose of this audit—quite frankly, far from it. Compass’s analogy comparing the role of CMS auditors with that of government prosecutors is at best unpersuasive, and at worst wholly inappropriate. (ECF No. 53 at PageID 541–42.) Comparing zero-paid claims in audits with exculpatory Brady evidence in criminal cases is a stretch. (Id. at PageID 542.) A zero-paid claim does not prove that an overpayment on other claims was appropriate or lessen the amount of overall overpayment. If Compass wants to play the analogy game, it would be more apt to compare apples to apples rather than apples to starfruits.

The ALJ decisions that approved the exclusion of zero-paid claims from the sample sizes constituted adequate findings of fact, not potential errors of law. The correct legal standard was applied throughout the appeals process as well, including during the ALJ decisions that are before the Court. Zero-paid claims do not need to be included in sampling, and therefore their exclusion does not prejudice any hypothetical due process property interest that Compass may or may not have.

Because substantial evidence exists to support the factual findings made by the ALJs, the Secretary is entitled to judgment as a matter of law on the issues in counts one and counts two. As previously noted, the Secretary's motion discusses more issues that it interpreted as common across both of Compass's complaints. (ECF No. 56 at PageID 570–71.) The Court will not consider those issues at this time, and therefore cannot grant the Secretary's motion in full.

CONCLUSION

For these reasons, the Secretary's motion is **GRANTED IN PART** and Compass's motion is **DENIED**, and the two applicable counts concerning a potential due process violation around the universe of claims and the failure to include zero-paid claims in the sampling are **DISMISSED WITH PREJUDICE**. Per the Court's Order Granting Joint Motion for Extension of Time to File Dispositive Motions, the deadline to file dispositive motions relating to individual claims is four weeks from the date of entry of this Order. (See ECF No. 60 at PageID 592.)

IT IS SO ORDERED, this 26th day of March, 2024.

s/ Sheryl H. Lipman

SHERYL H. LIPMAN
CHIEF UNITED STATES DISTRICT JUDGE